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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/876,478 | 06/07/2001 | John A. Peyman | JP-001 | 8914 |

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Dr. John A. Peyman
336 West Rock Avenue
New Haven, CT 06515

| EXAMINER | |
|---|---|
| BASI, NIRMAL SINGH | |
| **ART UNIT** | **PAPER NUMBER** |
| 1646 | |

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/876,478 | PEYMAN, JOHN A. | |
| | Examiner | Art Unit | |
| | Basi N [illegible] | 1646 | |

*-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 October 2003*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *2-8 and 10-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

## DETAILED ACTION

1. Applicant's election with traverse of Group I (Claims 1, 3, 4, 5 and 9 ) on 10/28/03, is acknowledged. The traversal is on the ground(s) that, although invention I and the method of Inventions III and V are related as product and process of use, as are Invention II and the methods of Invention IV and VI, the products as claimed can not be used in a materially different process. Further Applicant argues it would not be a serious burden to examine the groups together. This is not found persuasive because a search of groups I-VI would not be co-extensive particularly with regard to the literature search. The product of Inventions I and II can be used to raise antibodies (materially different process) , said antibodies may be produced so a to specifically bind to the antigen used to raise them. An examination of the materially different, patentably distinct inventions in a single application would constitute a serious undue burden on the examiner. Claims 1-2, 6-8, 10-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

### Objections

2. Applicants are required to use the heading "Brief Description of the Drawings" to describe the drawings. See MPEP 608.01(f). On page 11, Applicant has written Brief Description of the Figures.

Appropriate correction is required.

Figures 7, 9 and 11 must also be described in the Brief Description of the Drawings as Figures 7A-B, 9A-B,11A-C. Appropriate correction is required.

3. The disclosure is objected to because of the following informalities:

Nucleotide sequences in the Figures must be must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. Figure 3 contains 2 sequences only one sequence identified is disclosed in the Brief Description of the Drawings. The same applies to Figures 4-6 and 9. Appropriate correction is required. Further the sequence identifier of SEQ ID NO:4 does represent VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY. The specification and the claims require the correct sequence identifier for VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY. Correction is required throughout the specification and the claims.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The paper copy of the sequence listing and the CRF do not contain the correct sequence of VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY, identified as SEQ ID NO:4

***Claim Rejections - 35 USC § 112, Second Paragraph***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 is indefinite because the ISPLP, VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY, is identified by SEQ ID NO:4, which is the incorrect sequence identifier. The ISPLP, VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY, must be identified by the correct SEQ ID NO:.

The term "substantially" in claim 1 is a relative terms which renders the claim indefinite. The term "substantially identical to SEQ ID NO:4" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. It is not clear when an amino acid sequence is substantially identical to SEQ ID NO:4 as compared to when it is not substantially identical to SEQ ID NO:4.

The term "derivative" is indefinite because it provides no information about the structure of SEQ ID NO:4 or an amino acid sequence with

substantial identity to SEQ ID NO:4, and encompasses an infinite number of possibilities.

Claims 3, 4, 5 and 9 are rejected for depending upon indefinite base (or intermediate) claim and fail to resolve the issues raised above..

5. ***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for ISPLP comprising VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY, which suppresses IFN-gamma-stimulated expression of MHC class II antigens, MHC class I antigens and ICAM-1 does not reasonably provide enablement for other ISPLP compounds which are derivatives of VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY or compounds with substantial identity to VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification has disclosed ISPLP, VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY, which suppresses IFN-gamma-stimulated expression of MHC class II antigens, MHC class I antigens and ICAM-

1. The critical structural feature of the invention is the N-terminal 28 residues of hPL, VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY, which are required for activity. While the person of ordinary skill in the art would, in light of the specification be able to use the 28 amino acid peptide, VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY to suppresses IFN-gamma-stimulated expression of MHC class II antigens, MHC class I antigens and ICAM-1, there is no disclosure in the specification or prior art that variants with substantial identity to SEQ ID NO:4 or derivatives of SEQ ID NO:4 (comprising as little as 5 residues) can be used to suppresses IFN-gamma-stimulated expression of MHC class II antigens, MHC class I antigens and ICAM-1. The scope of the claims, which encompass other peptides, apart from VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY, are not enabled by the disclosure. The disclosure does not teach how to make or identify such variants, or to use a commensurate number of the variants which did not share all the functional properties encompassed by the peptide of VQTVPLSRLFDHAMAMLQAHRAHQLAID. Due to the large quantity of experimentation necessary to identify the polypeptides used in instant method, the lack of direction/guidance presented in the specification regarding the production, identification, purification, isolation and characterization of said polypeptides, the unpredictability of the effects of mutation on the structure and function of proteins (since mutations of VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY are also encompassed by the claim), and the breadth of the claim which fail to recite structural critical feature of

the invention required for activity, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

6. Claims 1, 3-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

Claims are drawn to derivatives of VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY or compounds with substantial identity to VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY, which suppresses IFN-gamma-stimulated expression of MHC class II antigens, MHC class I antigens and ICAM-1. The specification discloses VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY, which suppresses IFN-gamma-stimulated expression of MHC class II antigens, MHC class I antigens and ICAM-1. The instant disclosure of the polypeptide VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY does not adequately describe the scope of the use of claimed genus, which encompasses a substantial variety of subgenera including full-length, truncated, fusion polypeptides derivatives and variants thereof. The critical feature of the invention required for activity is the

polypeptide comprising VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY. A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by an amino acid sequence, falling within the scope of the genus or of a recitation of structural and functional features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural and functional features of the claimed genus of polypeptides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. The fusion polypeptides, fragments, derivatives and variants encompassed by the claims do not disclose the critical technical feature of the claimed invention required for function. For example, which 5 residues, alone, function to suppress IFN-gamma-stimulated expression of MHC class II antigens, MHC class I antigens and ICAM-1. The critical technical feature encompassed by the substantially identical polypeptides or derivatives of VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY must relate the encompassed critical structural feature of the polypeptide to its function. It is not clear what critical technical feature the variants or derivatives provide so as to show a written description of the invention in full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing. The specification proposes to discover other members of the genus. There is no

description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

The specification further fails to identify and describe the regulatory regions essential to the function of the VQTVPLSRLFDHAMAMLQAHRAHQLAIDTY polypeptide since the claimed invention currently encompasses the full length, truncated, fusion polypeptides, derivatives and variants thereof. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus may be highly variant, the disclosure is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 703-308-9435. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Nirmal S. Basi
Art Unit 1646
11/17/03

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600